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Philips Healthcare

June 25, 2010

Federal Communications Commission
Office of the Secretary
445 12th St. SW
Washington, DC 20554

Subject: FCC Docket No. ET 10-120

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., Bldg. 66, Rm. 3543
Silver Spring, MD 20993
FDA Docket No. FDA-2010-N-0291

To: Federal Communications Commission
Food and Drug Administration, Center for Devices and Radiological Health

Philips Healthcare (Philips) is pleased to submit the comments below concerning the joint FCC- FDA public meeting on regulatory issues arising from health care devices that incorporate radio technology in wireless communications networks. Philips is the world leader in patient monitoring equipment and one of the largest suppliers of medical equipment in the United States.

Philips is pleased that the FCC and FDA will jointly address regulatory issues related to wireless medical devices and devices that integrate broadband communications. Demand for wireless monitoring devices in particular is steadily increasing. More and more medical sites of service use wireless devices for monitoring as they provide a higher standard of care with better patient results. Philips' wireless monitoring devices blend wired and wireless communications with seamless handoff so that patients now can be monitored continuously, even while exercising and moving about.

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In response to the Public Notice, Philips respectfully submits the following suggestions for the joint meeting.

- Wireless monitoring and broadband connectivity facilitates compiling and transmitting comprehensive patient records to all medical providers concerned with a patient. As the FCC recognized in Chapter 10 of its Broadband Report, the Office of the National Coordinator for Health Information Technology (ONC) oversees the initiative for electronic health care records (EHRs). Given the applicability of gathering and transmitting EHR information over broadband connections, the agencies may consider participation by the ONC in the joint meeting.

- To clarify and provide guidance to medical device manufacturers, the FCC and FDA should consider adopting a Memorandum of Understanding between the agencies that more clearly defines the jurisdictions of each agency with regard to wireless medical devices. In this regard we note in particular the FDA's authority to ensure the safety of medical devices and the FCC's authority to regulate spectrum use for wireless medical devices.

- The FDA should address and resolve any issues necessary in order to finalize its "Draft Guidance for Industry and FDA Staff, Radio-Frequency Wireless Technology in Medical Devices" that was issued on January 3, 2007 but not yet adopted in final form.

- With regard to Questions A, C and D (reliability, spectrum, and risk), the safe use of secondary spectrum allocations, as well as primary spectrum allocations, should be discussed. In this regard, Philips notes that for many years wireless medical devices have safely used secondary spectrum allocations and more recent primary allocations complement but do not replace this use.

- With regard to Questions A and E, discuss the need for developers of new medical technologies (products that use technologies not previously used in health care facilities) to assess their potential for interference with existing medical devices.

Philips is happy to provide these comments and looks forward to participating in the meeting to help address and clarify these and other regulatory issues related to medical devices that use wireless and/or broadband technologies.

Respectfully,

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